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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,989	05/29/2001	Wilfred Wayne Lauth	2495.00071	7861

7590 09/17/2003

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/17/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,989

Applicant(s)

LAUTT, WILFRED WAYNE

Examiner

Cybille Delacroix-Muirheid

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 9-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4 and 9-13 is/are allowed.
- 6) ☒ Claim(s) 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

Claim 14 is rejected under 35 U.S.C. 102(e) as being anticipated by Adams et al., 6,165,975. (already of record).

Claim 14 is rejected under 35 U.S.C. 102(e) as being anticipated by Papandreou et al., 6,171,232. (Already of record).

Claims 14 is rejected under 35 U.S.C. 102(e) as being anticipated by Salzman et al., 5,958,427. (Already of record)

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by either Klokke-Bethke et al., 5,370,862 or Veronesi et al., 5,580,576.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al., 6,165,975 or Papandreou et al., 6,171,232 or Salzman et al., 5,958,427 or Klokke-Bethke et al., 5,370,862 or Veronesi et al., 5,580,576.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to Applicant's amendment received May 19, 2003.

Claim 5 is cancelled. No new claims are added. Claims 1-4, 9-18 are currently pending.

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The previous claim rejection under 35 USC 112, paragraph 2, set forth in paragraphs 2-3 of the office action mailed Dec. 18, 2002 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous claim rejections under 35 USC 102(e), (b) and 35 USC 103(a), set forth in paragraphs 4-11 of the office action mailed Dec. 18, 2002 have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office action mailed Dec. 18, 2002 with the following additional comment:

It is essentially Applicant's position that none of the prior art references of Adams et al., Papandreou et al., Salzman et al., Klokke-Bethke et al. and Veronesi et al. disclose or fairly suggest the claimed pharmaceutical compositions and kit. Specifically, Applicant argues that the present invention is structurally distinct from the compositions of the prior art because the claims require the nitric oxide donor and nitric oxide agonist to be structurally adapted to preferentially release nitric oxide in the liver. Applicant contends that none of the prior art references teach the limitation and therefore do not anticipate the claims.

Concerning the rejection under 35 USC 103(a), Applicant argues that claim 16-18 are not directed to a composition. Instead, these claims are directed to a kit containing instructional material for using the nitric oxide donor or agonist in treating insulin resistance. Therefore, it would not be obvious to one of ordinary skill in the art to package the compositions into a kit with the claimed instructions.

Said arguments have been considered but are not found to be persuasive.

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The Examiner respectfully submits that claims 14 and 15 continue to be anticipated by the prior art. According to page 8, lines 10-15 of Applicant's specification the limitation "nitric oxide donors and agonists" encompasses a number of compounds such as SIN-1, SNAP, sodium nitrite and nitroprusside. Therefore, the Examiner submits that although the references don't specifically disclose that the donor or agonist is "structurally adapted to preferentially release nitric oxide from the liver", the references do disclose compositions containing compounds (nitroglycerin, nicorandil, SNAP, sodium nitroprusside) that encompassed by the claims. Therefore, the Examiner respectfully maintains that the prior art of record continues to anticipate Applicant's claimed compositions.

Concerning the previous rejection under 35 USC 103(a), although these references do not specifically disclose formulating the compositions into a kit containing structural material, the Examiner respectfully maintains that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the compositions of the prior art into kits because one of ordinary skill in the art would reasonably expect kit compositions to be a useful means for packaging pharmaceutical compositions for subsequent use in therapeutic treatment. Finally, the instructional material describing instructions for using the nitric oxide donor or agonist compositions relates to intended use and does not further limit or define the overall pharmaceutical compositions.

It is for these reasons that the rejection is maintained.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Tue-Thur. from 8:30 to 6:00. The examiner can also be reached on alternate Mondays .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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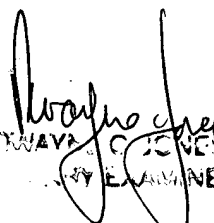
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CDM



Sept. 15, 2003



DWAYNE C. JONES
PATENT EXAMINER